

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MEDTECH PRODUCTS INC.,

Plaintiff,

v.

RANIR, LLC and
CVS PHARMACY, INC.

Defendant.

Civil Action No. 07 CV 03302-UA-LMS

MEDTECH PRODUCTS INC.,

Plaintiff,

v.

DENTEK ORAL CARE, INC.,

Defendant.

ECF FILED

MEDTECH PRODUCTS INC.,

Plaintiff,

v.

POWER PRODUCTS, INC.
d/b/a SPLINTEK,

Defendant.

PLAINTIFF MEDTECH PRODUCTS INC.'S
CLAIM CONSTRUCTION BRIEF

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Plaintiff Medtech Products, Inc. (“Medtech”), pursuant to this Court’s Discovery Plan and Scheduling Order entered on May 31, 2007, hereby submits its Claim Construction Brief in support of its constructions for the claim terms in dispute for Claim 17 of U.S. Patent No. 6,830,051 (the “‘051 Patent”), a copy of which is attached as *Exhibit A* for the Court’s convenience.

I. BACKGROUND

Medtech and its predecessor-in-interest pioneered the over-the-counter sale of dental protectors – products that are designed to protect the teeth and jaw from the detrimental effects of teeth grinding (known as bruxism). Medtech sells a dental protector that is the subject of the ‘051 Patent under the trademarks THE DOCTOR’S[®] NIGHTGUARD[™] and nationally generates more than ten million dollars in annual sales for Medtech.

Medtech owns the rights to the ‘051 Patent. The overall subject of the ‘051 Patent is an interocclusal appliance including a maxillary impression perform of a resilient thermoplastic having a low softening temperature, which is molded over and unitarily bonded to a bases having a planar bottom face contacted by mandibular occlusal surfaces. ‘051 Patent, abstract. In layman’s terms, the subject of the ‘051 Patent is a dental protector whose primary purpose is to prevent bruxing, i.e. grinding, and clenching, i.e. closing tightly, of the teeth. The dental protector is unique in that it may be fitted without the need for a dental professional. After dipping the dental protector in water of a high temperature and then briefly into cooler water, the user can form the dental protector to the unique configuration of the maxillary structures in his or her mouth.

DenTek has received a Section 510(k) premarket authorization from the Food and Drug Administration (“FDA”) for marketing of the DenTek dental protector product, based upon the

DenTek product being “substantially equivalent” to Medtech’s dental protector product. In its filings with the FDA, DenTek itself made the following assertion:

The DenTek NightGuard is substantially equivalent to The Doctor’s NightGuard. The DenTek NightGuard has the same intended uses, indications and principles of operation, and similar technological characteristics as its predicate device. The minor technological differences between the DenTek NightGuard and its predicate device raises no new questions of safety or effectiveness. Thus, the DenTek NightGuard is substantially equivalent to The Doctor’s NightGuard.

See Boyko Decl. ¶ 4 & Ex. 2, Civil Action No. 07 CV 03305, Docket Entry No. 12.

Testing of the DenTek product confirms that it has characteristics that infringe one or more claims of the ‘051 Patent. In particular, claim 17 of the ‘051 Patent recites:

17. A method of fabricating an interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events, the method comprising the steps of:

- a) molding and [sic] appliance base from a resin having a Vicat softening temperature of at least 70° C. and a Shore A hardness of at least 80; and
- b) molding over the base an impression preform from a resin comprising an ethylene vinyl acetate copolymer having approximately 30% by weight vinyl acetate.

Schrank Decl. ¶ 14, Ex. L, Civil Action No. 07 CV 03305, Docket Entry No. 10. Testing demonstrates that the DenTek product has an appliance base molded from a resin having a Vicat softening temperature of 87° C (+/- 5° C), and a Shore A hardness of 87.4 (+/- 2.3), with an impression preform molded over the base, the impression preform comprising an ethylene vinyl acetate copolymer having 34.3% by weight vinyl acetate.

DenTek asserts a narrow construction of terms contained in Claim 17 such that its product will be outside the scope of the ‘051 Patent. In so doing, however, DenTek has asserted construction of terms that are inconsistent with the common and ordinary meaning as understood by one with ordinary skill in the relevant art and/or inconsistent with the intrinsic record.

II. THE PARTIES CLAIM CONSTRUCTION CONFERRAL PROCESS

Pursuant to the Discovery Plan and Scheduling Order entered by this Court, the parties exchanged lists of terms included in Claim 17 of the '051 Patent to be construed. These exchanges were made on or about June 15, 2007 and are attached hereto as ***Exhibit B*** and ***C***. The parties identified the following terms to be construed:

1. an interocclusal appliance
2. molding and appliance base
3. a resin
4. having a Vicat softening temperature
5. of at least 70°C
6. a Shore A hardness
7. of at least 80
8. molding over the base
9. an impression perform
10. a resin
11. an ethylene vinyl acetate copolymer
12. having approximately 30% by weight vinyl acetate

On or about June 22, 2007, the parties exchanged initial proposed claim constructions for the above terms. Copies of the Plaintiff's Initial Proposed Claim Construction and Defendant DenTek's Preliminary Proposed Construction of Claim 17 of the '051 Patent are attached hereto as ***Exhibits D*** and ***E***, respectively. However, when DenTek submitted proposed constructions for the above terms on June 22, 2007, it added the terms "bruxing" and "clenching". Plaintiff objects to the addition "bruxing" and "clenching" because such terms were not timely submitted

in accordance with the Discovery Plan and Scheduling Order. Accordingly, the above twelve (12) terms, and not “bruxing” and “clenching”, are the subjects of this brief.

III. PRINCIPLES OF CLAIM CONSTRUCTION

“It is a ‘bedrock principle’ of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citations omitted). Accordingly, “claim construction analysis must begin and remain centered on the claim language itself, for that is the language that the patentee has chosen to ‘particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.’” *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004) (quoting *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001)). The role of claim construction “is neither to limit nor to broaden the claim, but to define, as a matter of law, the invention that has been patented.” *Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2005).

Claim construction always begins with the language of the claim itself. *See Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999); *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed.Cir.1998). The words of a claim “are generally given their ordinary and customary meaning.” *Phillips*, 415 F.3d at 1313 (citations omitted). It is well established that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the relevant art at the time of the invention, i.e., as of the effective filing date of the patent application. *Id.* Unless otherwise compelled, a court should give full effect to the ordinary meaning of claim terms even if the terms are broad. *Johnson Worldwide*, 175 F.3d at 989.

The claims, however, are not construed in a vacuum. *Toro Co. v. White Consolidated Indus., Inc.*, 199 F.3d 1295, 1301 (Fed. Cir. 1999) (“The claim word ‘including’ is not construed

in a lexicographic vacuum, but in the context of the specification and drawings.”). If the ordinary meaning of claim language as understood by a person of skill in the relevant art is not readily apparent, a court may determine the ordinary and customary meaning of the term by looking beyond the claims to the specification of the patent, the prosecution history or the patent, and prior art references cited during the prosecution history of the patent. *Phillips*, 415 F.3d at 1312. “In order to overcome this heavy presumption in favor of the ordinary meaning of claim language, it is clear that ‘a party wishing to use statements in the written description to confine or otherwise affect a patent’s scope, must, at the very least, point to a term or terms in the claim with which to draw in those statements.’” *Johnson Worldwide* at 989 (quoting *Renishaw*, 158 F.3d at 1248). In an appropriate case, the specification often is the single best guide to the meaning of a disputed term. *Phillips*, 1303 at 1312.

However, there is a “thin line” between reading a claim in light of the specification and the well-established principle that the specification cannot import limitations into the claims. *Comark Comm., Inc. v. Harris Corp.*, 156 F.3d 1182, 1186-87 (Fed. Cir. 1998); *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 345 F.3d 1318, 1327 (Fed. Cir. 2003). If a claim term is readily apparent to one with ordinary skill in the relevant art, then consideration of the specification and the prosecution history is typically limited to confirming whether the ordinary meaning applies or whether the patentee intended to deviate from this meaning. *Interactive Gift Express*, 256 F.3d at 1331; *Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1179 (9th Cir. 2006) (holding that district court improperly imported limitations from specification when interpreting claim term). The Federal Circuit has repeatedly recognized that there is a difference between construing a term appearing in a claim, and adding a limitation that is not there in the first place. The former is permissible; the latter is not. *See, e.g., Interactive Gift Express*, 256

F.3d at 1331-32 (“in looking to the specification to construe claim terms, care must be taken to avoid reading limitations appearing in the specification . . . into [the] claims”) (citations omitted); *Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1340 (Fed. Cir. 1999) (“Consistent with the principle that the patented invention is defined by the claims, we have often held that limitations cannot be read into the claims from the specification or the prosecution history.”); *Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1348 (Fed. Cir. 1998) (“interpreting what is meant by a word and a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper”). In *Liebel-Flarsheim Co. v. Medrad, Inc.*, the Federal Circuit noted that the key to looking to the specification is to view it “without unnecessarily importing limitations from the specification into the claims.” 385 F.3d 898 (Fed. Cir. 2004) (citations omitted). “These two rules lay out the general relationship between the claims and written description.” *Renishaw*, 158 F.3d at 1248.

It is particularly inappropriate to import attributes of the preferred embodiment portion of the specification into the claims as limitations. *Innova/Pure Water*, 381 F.3d at 1117; *see also Burke*, 183 F.3d at 1341. “References to a preferred embodiment, such as those often present in a specification, are not claim limitations.” *Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 865 (Fed. Cir. 1988). “This court has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification.” *Texas Instruments, Inc. v. United States Int’l Trade Comm’n*, 805 F.2d 1558, 1563 (Fed. Cir. 1986). “Although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.” *Acumed, LLC v. Stryker Corp.*, 82 U.S.P.Q.2d 1481, 1485 (Fed. Cir. 2007) (citing *Phillips*, 415 F.3d at 1323) (holding that specification did not limit claim term).

Notwithstanding the principle that limitations should not be imported from the specification, there are instances where doing so may be warranted. If a specification expressly and implicitly defines a term, the specification can be used to limit the scope of the term in a claim. *Phillips*, 415 F.3d at 1316; *Astrazeneca AB v. Mutual Pharmaceuticals Company*, 384 F.3d 1333, 1339-1340 (Fed. Cir. 2004). “[A] patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (9th Cir. 1996) (citation omitted); *see also Johnson Worldwide*, 175 F.3d at 990. Although previous Federal Circuit decisions, such as *Vitronics Corp.*, have held that when a patentee intends to be its own lexicographer it must “expressly” define the terms, recent Federal Circuit decisions have declined to required such “rigid formalism” and have permitted terms to be defined by implication from the language of the specification. *Astrazeneca AB*, 384 F.3d at 1340; *Bell Atl. Network Servs., Inc. v. Covad Comm. Group, Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001); *cf. Vitronics*, 90 F.3d at 1582 (“The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.”); *York Products, Inc., v. Central Tractor Farm & Family Center*, 99 F.3d 1568, 1572 (Fed. Cir. 1996) (“Without an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning.”)

A specification also may be used to limit the claims if there is an intentional disclaimer present in the specification. “In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In that instance as well, the inventor has dictated the correct claim scope, and the inventor's intention, as expressed in the specification, is regarded as dispositive.” *Phillips*, 415 F.3d at 1316. This disclaimer need not

be expressly made. *Astrazeneca AB*, 384 F.3d at 1340. For example, a disclaimer may be implied where the general summary or description of the invention describes a feature of the invention and criticizes other products that lack that same feature. *Id.*

Definitions that arise from extrinsic evidence may be used but are limited by the intrinsic evidence. In *Phillips*, the Federal Circuit indicated that it is appropriate to use dictionary definitions when construing claim terms and to “assist in the understanding the commonly understood words.” 415 F.3d at 1322 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 n.6 (Fed. Cir. 1996)). The Federal Circuit reaffirmed this position in *Free Motion Fitness, Inc. v. Cybex Int’l, Inc.*, 423 F.3d 1343 (Fed. Cir. 2005), where it stated, “In those circumstances where reference to dictionaries is appropriate, the task is to scrutinize the intrinsic evidence in order to determine the most appropriate definition.” *Id.* at 1349 (citing *Phillips*, 415 F.3d at 1322-23, 1324) (using Webster’s Third New International Dictionary to confirm the definition of “adjacent” in the specification).

Subsequent Federal Circuit decisions have interpreted *Phillips* to mean that extrinsic sources such as dictionaries may be used in one of two situations. First, dictionaries may be used to confirm the definition supported by the intrinsic evidence. *Nystrom v. Trex Co., Inc.*, 424 F.3d 1136, 1145-46 (Fed. Cir. 2005); *AquaTex Indus., Inc. v. Techniche Solutions*, 419 F.3d 1374, 1381 (Fed. Cir. 2005)(using dictionary to confirm intrinsic evidence of the meaning of “fiberfill”); *Terlap v. Brinkmann Corp.*, 76 USPQ2d 1053, 1057 (Fed. Cir. Aug. 16, 2005). Dictionary definitions may even be used as a starting point in claim interpretation so long as the analysis of claim construction is “centered around the intrinsic record.” *Old Town Canoe Co. v. Confluence Holdings, Corp.*, 78 USPQ2d 1705, 1710 (Fed. Cir. May 9, 2006). A dictionary

definition, however, may not be used to broaden the definition of a word in such a way as to be inconsistent with the intrinsic evidence of the patent. *Nystrom*, 424 F.3d at 1145-46.

Second, it is appropriate to look to dictionaries, including scientific and technical dictionaries, to construe the ordinary and customary meaning of a word when there is “no suggestion in the intrinsic evidence” that defines a term. *Atofina v. Great Lakes Chemical Corp.*, 78 USPQ2d 1417, 1421 (Fed. Cir. March 23, 2006) (holding that dictionaries were properly consulted to determine the meaning of “catalyst”).

In the present case, Plaintiff’s claim constructions are supported by the intrinsic record and re-affirmed by the ordinary and customary usage of the terms as confirmed by dictionaries.

IV. PLAINTIFF’S CLAIM CONSTRUCTION

For the convenience of the Court, Claim 17 of the ‘051 patent is set forth below:

A method of fabricating an interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events, the method comprising the steps of:

a) molding and appliance base from a resin having a Vicat softening temperature of at least 70° C. and a Shore A hardness of at least 80; and

b) molding over the base an impression preform from a resin comprising an ethylene vinyl acetate copolymer having approximately 30% by weight vinyl acetate.

A. AN INTEROCCLUSAL APPLIANCE

Plaintiff believes this term that does not need to be defined as it is part of the preamble, and elements of the preamble generally are not restrictive claim elements, but merely provide context. However, to the extent necessary, Plaintiff defines this term as ***“an appliance that is used or fitted, in whole or in part, between portions of the upper and lower teeth.”***

DenTek defines this term as ***“a device that prevents full occlusion of all teeth.”***

Plaintiff’s construction of the term is the ordinary and customary construction of “interocclusal” used to in relation to the type of appliance that is subject of the ‘051 Patent.¹ Plaintiff’s construction of “interocclusal” is more accurate than DenTek’s construction. Merriam-Webster’s Medical Dictionary defines “interocclusal” as “situated or occurring between the occlusal surfaces of opposing teeth.” *See Exhibit F.* DentalGlossary.net similarly defines the term as the “space between upper and lower teeth.” *Id.* There is nothing inherent in the term “interocclusal appliance” that supports a definition requiring “full occlusion of all teeth.” Plaintiff’s construction correctly describes the placement of the appliance as between the upper and lower teeth of the user.

Plaintiff’s construction is consistent with the intrinsic evidence. The language of the other claims is replete with references to placing the appliance between the occlusal surfaces of the teeth. *See* Claims 12, 13, 15, 16. Moreover, the specification of the ‘051 Patent specifically references the placement of the invention. In the summary, it states that the device is to be molded against the maxillary arch of the user. Col. 2: 18-24.² It also is clear from Figs. 1 and 2 of the ‘051 Patent that the claimed invention is to be placed in the user’s mouth between the upper and lower teeth. Contrary to DenTek’s construction, there is nothing in the claims or the specification to suggest that Plaintiff’s dental appliance must prevent occlusion of “all teeth.”

Accordingly, Plaintiff’s construction of this term is more accurate than DenTek’s and should be adopted by the Court.

¹ Plaintiff does not distinguish between the terms “appliance” and “device” in this context, and is willing to amend its definition to ***“an appliance or device that is...”***

² All such references are to the column and line numbers of the ‘051 Patent specification. *See Exhibit A.*

B. MOLDING AND [SIC] APPLIANCE BASE

Plaintiff defines this claim element as *“a step of molding an appliance base.”*

DenTek objects to Claim 17 as indefinite, vague, and unclear in the recitation of this term, but also defines these terms as follows:

“molding” means *“forming a thermoplastic material into a particular shape by injecting the thermoplastic material into a mold”*

“appliance base” means *“a structure in which the thickness thereof is not significantly reduced by compressive forces applied by biting”*

Plaintiff’s construction is consistent with the plain language of Claim 17, which simply provides a step in a method for fabricating the interocclusal appliance. (It is self-evident that the word “and” is a typographical error, and should be the word “an”). This term is contained in the clearly delineated first of two steps to such fabrication.

To the extent that the Court desires guidance as to the specific terms “molding” and “appliance base,” the plain meaning of these words differs from DenTek’s proposed definitions.

The plain, ordinary meaning of “molding” is as follows:

1. To shape in or on a mold;
- 2a. To form into a particular shape; give shape to;
- 2b. To guide or determine the growth or development of in; influence;
3. To fit closely by following the contours of;
4. To make a mold of or from before casting;
5. To ornament with moldings.

See American Heritage College Dictionary, p. 878. *See Exhibit G.* The Random House Dictionary at p. 859 similarly defines molding as “the act or process of molding or shaping.” *See id.*

DenTek's construction seeks to impose limitations from the preferred embodiment into Claim 17. The '051 Patent, in referring to the preferred embodiments, states that "the base is formed by injection molding a thermoplastic resin having requisite characteristics into a base mold cavity." Col. 5: 6-8. The importation of this limitation from the preferred embodiment portion of the specification into the claims is improper. *Innova/Pure Water*, 381 F.3d at 1117; *see also Burke*, 183 F.3d at 1341. "References to a preferred embodiment, such as those often present in a specification, are not claim limitations." *Laitram Corp.*, 863 F.2d at 865.

The plain, ordinary meaning of "appliance base" is, of course, the "base of the appliance." The specification describes the appliance as comprising two parts, a lower part (the base) and an upper part (the impression preform). Col. 2: 3-4; col. 3: 1-3. The base being the lower part of the appliance on which the impression preform is placed is supported by the plain, ordinary meaning of the word "base," as shown in its dictionary definition. "Base" is a word with several meanings in different contexts. *See Exhibit H*. In this context, the most common definition fits: "the bottom support of anything; that on which a thing stands or rests." *Id.*

DenTek imports limitations regarding thickness and compressive forces that are not in the claim. While these may be part of a preferred embodiment, importation of limitations from the specification into the claim is not proper. *Innova/Pure Water*, 381 F.3d at 1117; *see also Burke*, 183 F.3d at 1341. The only limitations that should be applied to the base are those immediately following the term: "from a resin having a Vicat softening temperature of at least 70°C and a Shore A hardness of at least 80." The language of Claim 17, in itself, defines any and all limitations applicable to the "appliance base".

Based upon the plain, ordinary meaning of these terms, Plaintiff proposes the following compromise definition: *“the step of forming or shaping the bottom support or layer of the appliance.”*

C. **A RESIN**

Plaintiff proposes to define this term as *“a moldable material.”*

DenTek defines this term as *“a synthetic organic compound consisting of a noncrystalline solid or viscous liquid substance.”*

The term “resin” should be construed to have its ordinary and customary meaning that is consistent with the intrinsic record. Although “resin” is not explicitly defined within the ‘051 Patent, the common and ordinary definition of “resin,” as confirmed by The American Heritage College Dictionary, is the following:

1. Any numerous clear to translucent yellow or brown, solid or semisolid viscous substances of plant origin, such as amber, used in lacquers, varnishes, inks, and plastics.
2. Any of numerous physically similar polymerized synthetics or chemically modified natural resins including thermoplastic material such as polyethylene and thermosetting materials such as polyesters that are used with stabilizers and other components to form plastics.

Id. at 1161. See ***Exhibit I***.

In the context of the ‘051 Patent, no specific type of resin is specified. Indeed, the specification states, “It should be appreciated that the foregoing is merely exemplary and various other and alternate thermoplastic resins may be selected for use in accordance with the invention.” Col. 10: 29-33. The references to synthetic resins in the exemplars in the ‘051 Patent do not limit the types of resins that are available for use with the invention. Rather, the resins that may be used with the invention as claimed are limited only by the particular suitable

softening temperature range and hardness of the base, as specified in the claim. *Id.* Accordingly, DenTek's construction should be rejected because it imposes limitations, particularly the limitation of "synthetic", that are inconsistent with the ordinary meaning and the intrinsic record.

Based upon the plain, ordinary meaning of this term, Plaintiff proposes the following compromise definition: ***"any of a number of organic or synthetic solid or semi-solid substances or compounds, which may include thermoplastic or thermosetting materials."***

D. HAVING A VICAT SOFTENING TEMPERATURE

Plaintiff defines this term as ***"the temperature at which a flat-ended needle penetrates a specimen of the resin to the depth of 1 mm under a 10 Newton load, under STM D1525 standard."***

DenTek defines this term as ***"a temperature at which a flat-needle penetrates a specimen of the hardened resin to the depth of 1 mm under a specific load when the hardened resin is heated."***

The parties' definitions are essentially the same, based upon an established scientific standard. Plaintiff's definition does not, however, import the phrase "hardened" resin into the definition. Plaintiff proposes the following compromise definition: ***"a temperature at which a flat-needle penetrates a specimen of the resin to the depth of 1 mm under a specific load when the resin is heated."***

E. OF AT LEAST 70°C

Plaintiff defines this term as ***"a minimum Vicat softening temperature."***

Defendant defines this term as ***"a temperature of 70.0°C or more."***

The parties' definitions are simply different approaches to the same meaning. The term refers to and limits the preceding words in the sentence in which it is contained. Specifically, "of at least 70°C" refers to and limits "having a Vicat temperature of". Accordingly, "of at least 70°C" defines the minimum Vicat softening temperature required for the appliance base, which is "a temperature of 70.0°C or more."

To the extent that this relationship is understood, Plaintiff agrees to Defendant's construction of this phrase as *"a temperature of 70.0°C or more."*

F. A SHORE A HARDNESS

Plaintiff defines this term as *"a measurement of hardness using a TMI Duromotor model number 4150 equipped with a Shore Durometer Hardness Type A."*

DenTek defines this term as *"a measurement of the extent of indentation of a hardened resin by the action of a Shore A durometer."*

The parties' definitions are essentially the same, based upon an established scientific standard. Plaintiff's definition does not import the phrase "of a hardened resin" into the definition. Plaintiff proposes the following compromise definition: *"a measurement of the extent of indentation by the action of a Shore A durometer."*

G. OF AT LEAST 80

Plaintiff defines this term as *"a minimum Shore A hardness."*

DenTek defines this term as *"a Shore A hardness of 80 or more."*

The parties' definitions are simply different approaches to the same meaning. The term refers to and limits the preceding words in the sentence in which it is contained. Specifically, "of

at least 80” refers to and limits “having . . . a Shore A hardness of”. Accordingly, “of at least 80” defines the minimum Shore A hardness required, which is “80 or more.”

Accordingly, Plaintiff agrees to Defendant’s proposed construction of this phrase as “*a Shore A hardness of 80 or more.*”

H. MOLDING OVER THE BASE

Plaintiff defines this term as “*a step of molding over the base.*”

DenTek defines this term as “*contacting a heated resin with the entire upper surface of the appliance base.*”

As discussed above, this term should be given its ordinary and customary meaning in the context of the intrinsic record. This term refers to the second step of fabricating an embodiment of the invention in which the impression perform is molded over the base to form the appliance. See Col. 2: 3-4; col. 11: 3-6; col. 12: 16-18. The plain and ordinary meaning of the terms “molding” and “base” are discussed above in the context of the step of molding the appliance base.

DenTek’s proposed definition seeks to import limitations that are not in the claim. In particular, there is no basis for import the limitation “*with the entire upper surface*” into this claim.

Accordingly, Plaintiff now proposes the following compromise definition: “*the step of forming or shaping the impression preform of the appliance on the appliance base.*”

I. AN IMPRESSION PREFORM

Plaintiff defines this term as “*a formable material overlying the base.*”

Defendant defines this term as ***“a hardened resin structure containing a channel with curving sides and a flat bottom, and a footing that extends from a horizontal upper surface of the base to the channel face.”***

This term should be given its ordinary and customary meaning. Claim 17 defines the necessary process to fabricate the claimed dental protector. At its most basic level, the dental protector is a formable material that captures the unique structure of the user’s teeth that bonds to a base to prevent bruxing or clenching. *See* Col. 2: 3-4, 14-24; col. 3: 1-3.

DenTek seeks to import the limitations of Claim 1 into Claim 17. This is improper. The fact that specific structural elements were used in Claim 1 and not in Claim 17, in fact, demonstrates that the scope of the two claims differs. Claim 17 is a stand-alone, independent claim, not a dependent claim. If the applicant had intended to limit the scope of Claim 17 to the specific structure recited in Claim 1, it would have included that language, as it did in independent Claims 1 and 13.

J. A RESIN

Plaintiff defines this term as ***“a moldable material.”***

DenTek defines this term as ***“a synthetic organic compound consisting of a noncrystalline solid or viscous liquid substance.”***

This term has been discussed above in the context of the appliance base. *See* § C above. Based upon the plain, ordinary meaning of this term, Plaintiff proposes the following compromise definition: ***“any of a number of organic or synthetic solid or semi-solid substances or compounds, which may include thermoplastic or thermosetting materials”.***

K. AN ETHYLENE VINYL ACETATE COPOLYMER

Plaintiff defines this term as *“a resin made of copolymers of ethylene vinyl acetate.”*

DenTek defines this term as *“a single type of heteropolymer containing ethylene hydrocarbons interspersed with acetate groups, which does not include a mixture of two different types of such heteropolymers.”*

DenTek seeks to import a number of limitations into what is, in reality, a simple phrase. This term limits the preform resin to copolymers of ethylene vinyl acetate. Vinyl acetate is a chemical with a particular formula and is known by a variety of names. *See Exhibit J.* A common use is to combine it with ethylene (another chemical with a particular formula) to form ethylene vinyl acetate copolymers (i.e., copolymers of ethylene and vinyl acetate). *Id.* A “copolymer” is also known as a “heteropolymer,” and is a polymer derived from two or more monomeric species (in this case, the species are ethylene and vinyl acetate), as opposed to a homopolymer where only one monomer is used. *See Exhibit K.* Polymers are substances composed of molecules with repeating structural units. *See Exhibit L.*

The construction that this Court wishes to give to this phrase thus can vary in the amount of specificity. At a broad level, and assuming that there is no differences as to what “ethylene” and “vinyl acetate” are, Plaintiff suggests the following amended definition: **“copolymers or heteropolymers of vinyl acetate and ethylene,”** or more generally, **“a substance composed of vinyl acetate and ethylene.”** Vinyl acetate and ethylene can be defined with more specificity, if needed, but at this time, Plaintiff does not believe that the parties dispute what these chemicals are.

DenTek’s proposed construction errs in that it adds another limitation on top of the basic definition of copolymer or heteropolymer. DenTek seeks to limit the resin to a single type of copolymer/heteropolymer, whereas the claim is not so limited. The plain language of Claim 17

states that the resin “comprises” an ethylene vinyl acetate copolymer having approximately 30% by weight vinyl acetate. In patent terminology, “comprising” is used to mean “including at least the following elements.” See MPEP 2111.03 (“The transitional term ‘comprising’, which is synonymous with ‘including,’ ‘containing,’ or ‘characterized by,’ is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.”) (copy attached as ***Exhibit M***). In contrast, “consisting of” is used to mean “including only the following elements.” Claim 17 uses the open-ended “comprises,” thereby not limiting the resin to a single copolymer. The resin need only have at least one copolymer of EVA as stated; it is not limited to just one.

L. HAVING APPROXIMATELY 30% BY WEIGHT VINYL ACETATE

Plaintiff defines this term as ***“the resin has approximately 30% by weight vinyl acetate.”***

DenTek defines this term as ***“having at least 27.0% by weight vinyl acetate but not more than 33.0% by weight vinyl acetate.”***

The term “having approximately 30% by weight vinyl acetate” should be construed to have its ordinary and customary meaning in light of the intrinsic evidence. The intrinsic evidence demonstrates that “approximately” does not mean the range specified by DenTek (which appears to be calculated as adding or subtracting 10% to the cited figure of 30%). There is no support in the claim or the specification for importing this range into the claim.

The word “approximately” has the commonly understood definition of “about, close to, just about, some, roughly, more or less, around, or so.” See ***Exhibit N***. As the parties do not seem to dispute the phrase “by weight vinyl acetate,” Plaintiff proposes the following compromise definition: ***“having about, roughly, or around 30% by weight vinyl acetate.”*** It will then be up to the finder of fact to determine whether a particular measurement of the

impression preform layer of DenTek's appliance is about, roughly or around 30% by weight vinyl acetate.

As further basis for rejecting DenTek's proposed construction, Plaintiff notes that the specification notes that suitable resins for employment as the impression perform include an ethylene vinyl acetate (EVA) copolymer "available from the Du Pont under the trademark ELVAX® having a vinyl acetate content of at least 25%." Col. 6: 13-16. The intrinsic evidence thus specifically refers to an EVA copolymer outside the range suggested by DenTek.

Contrary to DenTek's construction, "approximately" is not defined as a specific percentage or incremental difference. This narrow construction is convenient for DenTek because its infringing product contains an impression preform comprising an ethylene vinyl acetate copolymer having 34.3% by weight vinyl acetate. Accordingly, DenTek's attempt to import a convenient incremental limitation into this term so as to avoid infringement should be rejected

V. CONCLUSION

For all of the foregoing reasons, Medtech respectfully requests its constructions of the above terms be adopted by the Court.

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Respectfully submitted,

ALSTON & BIRD LLP

By: s/ Amy Manning
Karl Geercken (KG 5897)
Amy Manning (AM 0338)
90 Park Avenue
New York, New York 10016-1387
(212) 210-9471 (phone)

(212) 210-9444 (facsimile)
karl.geercken@alston.com
amy.manning@alston.com

W. Edward Ramage, TN BPR No. 16261
BAKER, DONELSON, BEARMAN,
CALDWELL & BERKOWITZ, P.C.1800
Commerce Center, Suite 1000
211 Commerce Street
Nashville, Tennessee 37201
(615) 726-5600
eramage@bakerdonelson.com

Carl M. Davis II, GA Bar Number 207710
BAKER, DONELSON, BEARMAN,
CALDWELL & BERKOWITZ, P.C.1800
Six Concourse Parkway
Suite 3100
Atlanta, Georgia 30328
(678) 406-8700
cdavis@bakerdonelson.com

Micheline Kelly Johnson, TN BPR No. 13847
Clinton P. Sanko, TN BPR No. 23354
BAKER, DONELSON, BEARMAN,
CALDWELL & BERKOWITZ, P.C.
1800 Republic Centre
633 Chestnut Street
Chattanooga, Tennessee 37450-1800
(423) 756-2010
mjohnson@bakerdonelson.com
csanko@bakerdonelson.com

Of Counsel:

Todd R. David , GA BPR No. 206526
ALSTON & BIRD LLP
One Atlantic Center
1201 West Peachtree Street
Atlanta, Georgia 30309-3424
todd.david@alston.com

Attorneys for Plaintiff
Medtech Products Inc.